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Lundbeck Research USA, Inc.
Attention: Stephen G. Kalinchak, Legal
215 College Road
Paramus, NJ 07652

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,380,936

mail ad
OCT 4 2012
b7 draft

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,380,936, claims of which cover a method of preparing the human drug product SABRIL® (vigabatrin), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of December 9, 2010 (75 Fed. Reg. 76741), would be 5,337 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \text{RRP} - \text{PGRRP} - \text{DD} - \frac{1}{2}(\text{TP} - \text{PGTP})^1 \\ &= 10,205 - 4,868 - 0 - \frac{1}{2}(4,614 - 4,614) \\ &= 5,337 \text{ days (14.6 years)}\end{aligned}$$

Since the regulatory review period began September 14, 1981, before the patent issued (January 10, 1995), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From September 14, 1981, to and including May 2, 1994, and from May 2, 1994, to and including, January 10, 1995, is 4,868 days; this period is subtracted for the number of days occurring in the testing phase and approval phase according to the FDA's determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation,

¹ Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of $\frac{1}{2}(\text{TP} - \text{PGTP})$.

because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,380,936
Granted:	January 10, 1995
Original Expiration Date ² :	December 7, 2012
Applicant:	Patrick Casara
Owner of Record:	Lundbeck, Inc.
Title:	Process for Preparing 4-Amino-5-Hexenoic Acid
Product Trade Name:	SABRIL® (vigabatrin)
Term Extended:	5 years
Expiration Date of Extension:	December 7, 2019

²Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

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By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary Till at (571) 272-7755.



Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: SABRIL® (vigabatrin)
Docket No.: FDA-2010-E-0021

Attention: Beverly Friedman